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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,908	10/23/2000	Paul L. Hermonat	023533/0130	8355

22428 7590 10/21/2003

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EXAMINER	
CHISM, BILLY D	
ART UNIT	PAPER NUMBER
1654	19

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,908	Applicant(s) HERMONAT, PAUL L.	
	Examiner B. Dell Chism	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-20 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,9,11,14,15,17 and 18* is/are rejected.

7)☒ Claim(s) *4 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is in response to Paper No. 17, filed 11 July 2003. Claims 2, 4-20 and 46 are pending and under consideration. The Hermonat Declaration was considered.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 11 July 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Objections

Claims 4 and 9 are objected to because of the following informalities: claim 4 should contain the verb "is" prior to the term "obtained"; claim 9 should delete the [is] and insert --consists of--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. (Maintained) Claim 20 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro administration of the AAV Rep78 mutant for replication studies, it is not enabled for in vivo therapeutic uses. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The declaration provides evidence of a correlation between infection with wild type adeno associated virus and a reduced incidence of cervical cancer in the general population, however, it does not provide any evidence that a mutated adeno-associated virus vector can be administered in vivo so as to be therapeutically effective for treating cancer or other papillomavirus associated disease. The art teaches that the therapeutic efficacy of viral vectors administered in vivo is unpredictable. Smith 1995 (Annu. Rev. Microbiol. Vol. 49, pages 807-838) teach that long term replication of viral vectors administered in vivo is hampered by the inflammatory process, which results in the destruction of vector-treated cells (see page 828, last partial paragraph and page 829,last paragraph). Given the teachings of unpredictability that are found in the art, detailed teachings of how to make and administer the claimed viral vectors so as to treat papilloma associated disease or cancer are required. Neither applicants' disclosure nor the Hermonat Declaration provides such evidence. For these reasons, the rejections are maintained.

3. (New) Claims 2, 4-20 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an AAV Rep78 mutant which demonstrates enhanced binding to HPV16 and decreased binding to itself, is not enabled for increased or decreased binding for HIV and oncogenes as compared with wild type. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to an AAV Rep78 mutant which comprises an AAV Rep78 modified protein that binds to a DNA sequence from a papillomavirus, an AAV, an oncogene, or an HIV differently from the wild type. As set forth in applicant's specification at pages 4-5, the art teaches that AAV Rep78 is an AAV DNA biding transcription factor which inhibits bovine papillomavirus type 1 (BPV-1), HPV-16, and HPV-18 oncogenic transformation by inhibition of the PV promoter. Applicant's specification also sets forth that the art teaches that AAV Rep78 inhibits HIV by NDA binding at specific sequences of the HIV long terminal repeat promoter. Applicant's specification teaches how to make and use a mutant of AAV Rep78 that shows enhanced binding to HPV-16 and a mutant that has decreased binding with itself. However, the specification does not teach how to make a mutant that demonstrates either decreased or enhanced binding to either HIV or to an oncogene. There is no evidence either in the prior art or in applicant's specification that the disclosed mutants of A AAV Rep78 would demonstrate either enhanced or decreased binding of either an HIV or an oncogene. There is no guidance in applicant's specification as to how to make additional mutants that would demonstrate enhanced binding to either an HIV or an oncogene. There are no working examples disclosing mutants of AAV Rep78 with either enhanced or decreased binding to HIV DNA or to an oncogene. Absent such guidance, it would require undue experimentation by one of skill in the art to make and use the claimed mutants commensurate in scope with the claims.

4. (Maintained) Claim 11 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Applicant's arguments merely confirm what was stated in the previous office action that while there is enough information for one of skill in the art to make mutants with similar properties, reproduction of the identical virus is unpredictable. Further, Applicant has not provided any evidence that the starting material is readily available to the public and will be available for the life of the patent.

5. (Maintained) Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Even though Applicant has canceled the offending phrase, "containing at least the minimum number of amino acids...", the claim is still indefinite because it is unclear how long the truncated version must be (i.e., one still does not know the minimum number of amino acids required for the claimed binding). Furthermore, Applicant's use of the phrase "a truncated" depends directly from the limitation of the claimed truncated wild-type AAV Rep78 of claim 6; thus, any reference to the claim 6 truncated wild-type AAV Rep78 requires the use of the phrase "the truncated".

6. (New) Claims 14-15 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 and 17-18 are rejected as being indefinite for the lack of disclosure for the specific sequence for the tat protein of HIV and/or not providing a reference of the specific sequence.

Conclusions

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
15 October 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600